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Ensemble CMS

Central Monitoring System

USER MANUAL

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About this Manual

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Terms Used in this Manual

This guide is designed to give key concepts on safety precautions.

WARNING

A **WARNING** label advises against certain actions or situations that could result in personal injury or death.

CAUTION

A **CAUTION** label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

NOTE

A **NOTE** provides useful information regarding a function or a procedure.

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Chapter 1 Intended Use and Safety Guidance

1.1 Intended Use

ENSEMBLE CMS provides centralized monitoring and critical care management for patients monitored by MENNEN MEDICAL LTD. bedside monitors. From ENSEMBLE CMS, clinicians can gain access to patient information for patients on the Network. ENSEMBLE CMS displays waveforms, parameters and alarm status of MENNEN MEDICAL LTD. bedside monitors for up to 32 patients on a single screen or up to 64 patients using two screens.

1.2 Safety Guidance

To use the system safely and effectively and to avoid system failure, please read the user manual in detail and be familiar with the proper operation method. The following **WARNING** and **CAUTION** must be observed during the operation of the system. A **WARNING** label advises against certain actions or situations that could result in personal injury or death. A **CAUTION** label alerts the user to exercise care necessary for the safe and effective use of the ENSEMBLE CMS.

WARNING

1 The system should be installed by a qualified service engineer. Do not switch on power until all cables have been properly connected and verified.

2 The user of this system should get professional training and read this manual thoroughly before using it.

3 Do not use it in the presence of flammable anesthetic due to explosion risk.

4 To avoid the risk of electric shock, do not remove the unit covers.

5 Do not move the main unit and monitor while powering on the system.

6 Only the accessories supplied or recommended by the manufacturer can be connected to the system.

7 Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the standard IEC/EN 60601-1-1. Therefore anybody, who connects additional equipment to the signal input or output connector to configure a medical system, must make sure that it complies with the requirements of the valid version of the system standard IEC/EN60601-1-1. If in doubt, consult our technical service department or your local distributor.

8 Ensure that the environment in which the system is operated is not subject to any sources of strong electromagnetic interference, such as radio transmitters, mobile telephones, etc. Keep them far away.

9 This equipment must be used by or under the guide of physician. This equipment is not intended for home use.

WARNING

10 ENSEMBLE CMS system can only collect, supervise, record, store and display the information from Multi-parameter patient monitor but can not replace the monitoring function of the Multi-parameter patient monitor.

11 Ensure that the system can meet the requirements of standard IEC/EN 60601-1-1 before other devices are connected to the system. Other equipments connected to the interfaces of PC station must comply with the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore, all configurations should comply with the valid version of the system standard IEC/EN 60601-1-1. Everybody who connects additional equipment to the signal input connector or signal output connector configures a medical system, and is therefore responsible for the system complying with the requirements of the valid version of the system standard IEC/EN 60601-1-1. If in doubt, consult our technical service department or your local distributor.

12 The ENSEMBLE CMS can only be installed on the device recommended by MENNEN MEDICAL LTD..

13 Only use operating systems that are approved by MENNEN MEDICAL LTD., such as Windows 7. Using operating systems that are not approved by MENNEN MEDICAL LTD. may compromise the system performance and cause a potential hazard.

14 Do not rely on the information displayed on ENSEMBLE CMS to make therapeutic and diagnostic decisions. Please follow hospital guidelines and best clinical practices.

15 Clinical decision making based on the output of the device is left to the discretion of the provider.

16 Prior to intervening based on data displayed on the Central Monitoring System, providers must verify this data with the corresponding bedside monitor.

CAUTION

1 Federal (U.S.) Law restricts this device to sale by or on the order of a physician.

2 Read this manual prior to using this system.

3 The system should be used within temperature from +5□ to +40□.

4 Keep the environment clean. Avoid vibration. Keep it far from corrosive reagents, dust areas, high-temperature and humid environment.

5 The user must check that the equipment, cables and transducers do not have visible evidence of damage that may affect patient safety or monitoring capability before use. The recommended inspection interval is once per week or less. If damage is evident, replacement is recommended before using it.

6 Turn off the system power before connecting or disconnecting any accessory to the system.

CAUTION

7 Please do not operate the system if it is not operating normally or requires service.

8 Turn off the system power and remove the power cable before maintaining the system.

9 Preventive maintenance of the system including periodic cleaning and appearance checking can be finished by the user because this maintenance does not touch the interior.

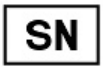
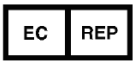
10 Avoid using attrite material to clean. Removing all dust from the exterior surface of the equipment with a soft brush or cloth or with a soft cloth, slightly dampened with a mild detergent solution or cool disinfector. Especially the tie-in and panel edge should be noticed.

11 Avoid pouring liquids on the equipment while cleaning, and do not immerse any parts of the equipment into any liquids.

12 The system data will be delayed for no more than 5 seconds.

NOTE:
The illustrations in this manual are for reference only.

1.3 Explanation of Symbols

	Consult Instructions For Use
	Serial number
	The symbol indicates that the device complies with the European Council Directive 93/42/EEC concerning medical devices.
	Authorized representative in the European community

	Date of manufacture
	Manufacturer
P/N	Part Number
	The symbol indicates that the device should be sent to the special agencies according to local regulations for separate collection after its useful life.
Rx only (U.S.)	Federal (U.S.) Law restricts this device to sale by or on the order of a physician.

Chapter 2 Introduction

2.1 General

ENSEMBLE CMS Central Monitoring System is a medical information device widely applied in clinical monitoring field. A monitoring network system is constructed by connecting multiple monitors. Being the center of the monitoring network, the system realizes central monitoring by collecting, processing, and analyzing the physiological information from multiple bedside monitors. The central system frees the doctors and nurses from multifarious clinical monitoring work and greatly improves monitoring quality.

This ENSEMBLE CMS is capable of connecting up to 64 bedside monitors that comply with the manufacturer network protocol.

This ENSEMBLE CMS connects bedside monitors via network and displays physiological information of the patients being monitored by bedside monitors. This system can simultaneously display the information from up to 64 bedside monitors.

Physiological waveforms of each bedside monitor that can be displayed on the ENSEMBLE CMS include:

- 2 ECG waveform
- 1 RESP waveform
- 1 PLETH waveform
- 8 IBP waveform
- 1 CO_2 waveform
- 4 AG waveforms for CO_2, O_2, N_2O and AA

Physiological parameters of each bedside monitor that can be displayed on the ENSEMBLE CMS include:

- ECG: HR, ST value, PVCs
- RESP: RR
- NIBP: SYS, DIA, MAP
- SpO_2: SpO_2, PR
- IBP: ART, PA, CVP, RAP, ICP, LAP, P1, P2 (only IBP supported by the monitor will be displayed)
- CO_2: $EtCO_2$, $FiCO_2$, AwRR
- TEMP: T1, T2, TD
- Quick TEMP
- AG: $EtCO_2$, $FiCO_2$, AwRR; EtO_2, FiO_2; EtN_2O, FiN_2O; HAL/ISO/ENF/SEV/DES: Et, Fi, MAC
- C.O.: C.O., TB

This ENSEMBLE CMS can also make notification in both audio and visual ways for the alarm occurring at the bedside monitor in order to attract the doctor's attention; as thus the alarm event can be dealt with accurately in time.

The ENSEMBLE CMS supports various kinds of peripheral devices such as printer that can output monitoring report. The typical central monitoring system network is shown in Figure 2-1:

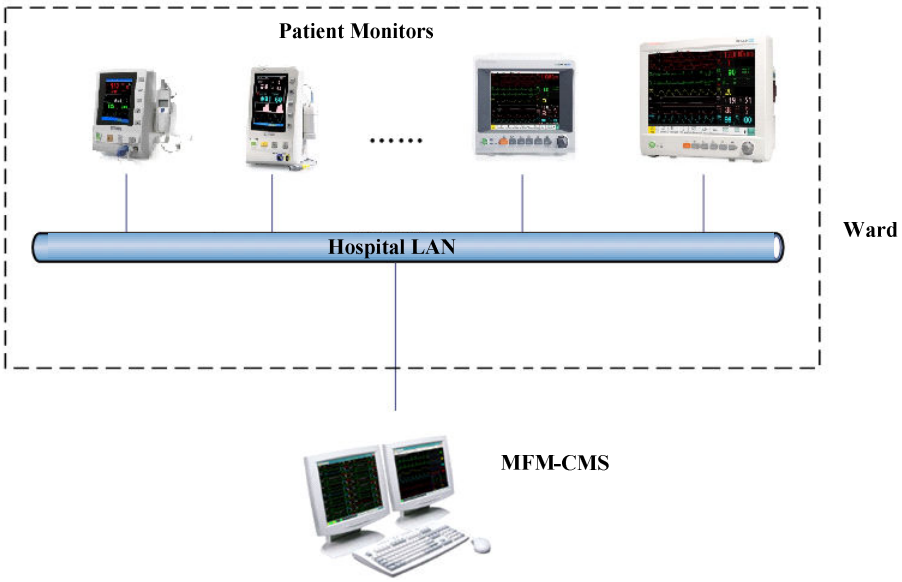


Figure 2-1 A Typical Central Monitoring System Network

2.2 System Functions

The ENSEMBLE CMS can realize the following system functions:

- Connecting of up to 64 bedside monitors simultaneously
- Alarm management of parameter alarms from bedside monitors
- Up to 240-hour of trend data storage and review for each bedside monitor
- 72-hour physiological waveforms
- Storage and review of up to 720 alarm events for each bedside monitor
- Up to 12-hour short trend review for each bedside monitor
- Review of 720 pieces of NIBP measurements
- Review of 720 pieces of 12-lead analysis results
- Review of 720 pieces of C.O. measurements
- Review of 720 pieces of Quick TEMP measurements
- Displaying multi-lead ECG
- Monitoring reports of review and alarm records can be output in a certain format
- Displaying single bed information for one bedside monitor
- Search, browse and maintaining management of patients' monitoring data

- Comprehensive system help function
- Power-off storage function available for all kinds of review information
- Calculation of drug doses and titration tables
- Hemodynamic Calculation
- Oxygenation Calculation
- Renal Function Calculation
- Ventilation Calculation
- Various alarm indicating methods
- Supporting wired connected monitor
- Web observation in the hospital local area network.
- Bilateral control
- HL7

2.3 Typical Screens of the ENSEMBLE CMS

The main screen of the ENSEMBLE CMS has three areas. At the top of the screen is the area displaying the system prompt information. The middle part is the main monitoring area. The bottom part is the system menu area.

The system will access the main screen automatically after power-on as shown in Figure 2-2. The main monitoring area displays 8 patient sections.

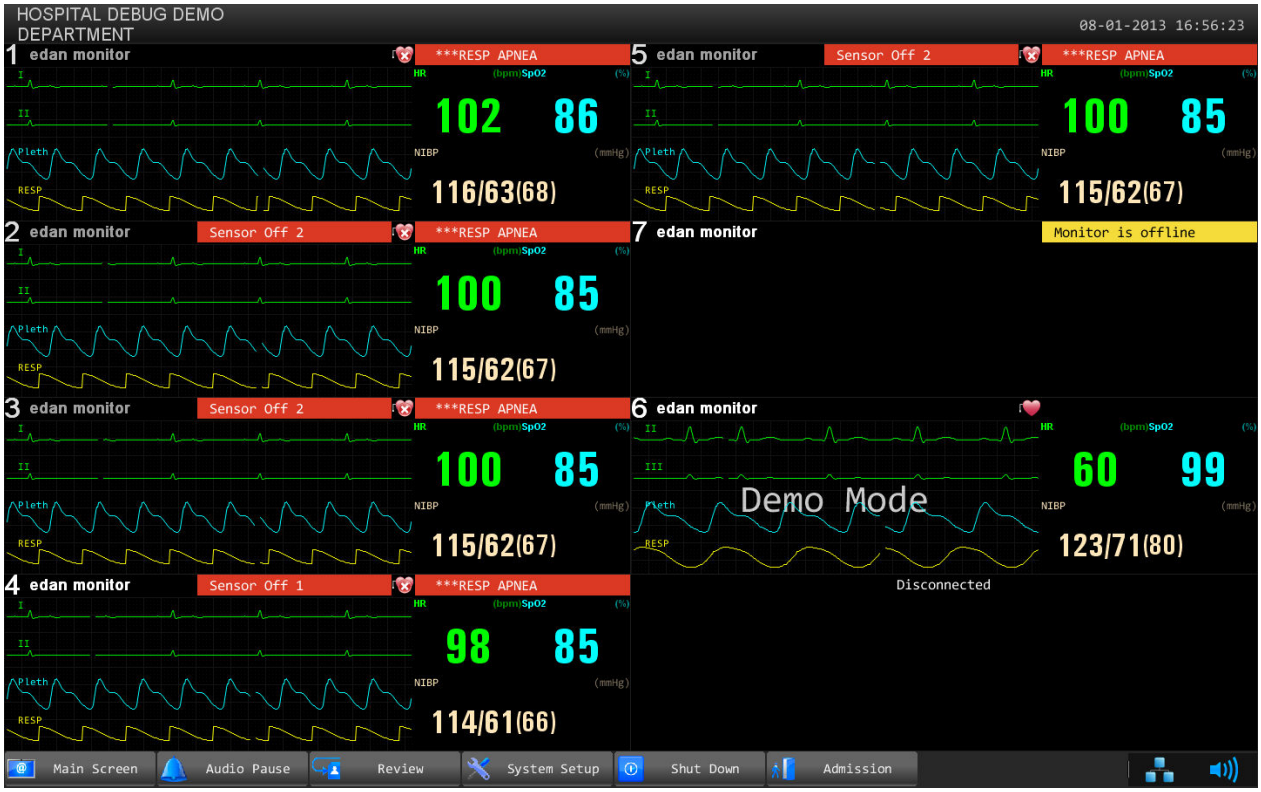


Figure 2-2 Main Screen

Structure of the main screen:

1. Main monitoring screen

- The black background with the white font **Disconnected** in a patient section indicates no bedside monitor is assigned to this patient section.
- The display of patient information and the low-level alarm message **Monitor is offline** in the patient section indicates the bedside monitor in this patient section is offline without being discharging. The system will indicate it with a low level alarm sound.
- The display of patient information, waveforms, trend data and alarm information indicates the bedside monitor is properly networked and under observation.
- Alarm area in the patient section: indicates physiological alarms and technical alarms. (Refer to *Chapter 6 Alarm Management* for more information about alarms.)
- The display of the symbols and :

  - The symbol indicates **Pace** is set to **On**;

  - The symbol indicates **Pace** is set to **Off**.

2. Information area

The information area is at the top of the screen. The hospital and department information is displayed on the left side of this area, the system time is displayed on the right side and the prompt messages are displayed in the middle.

3. Main menu

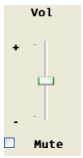
The main menu (Figure 2-3) is at the bottom of the screen. Click on it to access corresponding windows or perform corresponding functions.

Figure 2-3 Main Menu

4. Control icons

Control icon area includes the following icons:

Icons	Description	Operating method
	Main Screen	Click on it to return to the main screen.
	Audio Pause	Click on this symbol to make the alarm pause and the symbol appears in place of the symbol . And click on the symbol to deselect the pause function and the symbol appears in place of the symbol .
	Review	Click on it to enter the review interface, including patient information review, waveform review, alarm review, trend review and NIBP review.

	System Setup	Click on it to enter the system setup menu.
	Shut Down	Click on it to shut down the ENSEMBLE CMS and the operating system.
	Admission	Click on it to open the patient admission window.
	System Volume Adjustor	Click on it, the volume adjustor icon  appears. Select the **Mute** check box, and then enter the password in the text box on the pop-up window; the entire system become mute even if an alarm occurs, and the symbol appears. To deselect the silence function, tick the **Mute** check box again and the symbol appears. Additionally, the user can drag the volume adjustor to your desired volume.
	Network Connecting	Click on it to view all networked bedside monitors.

2.4 Large Font Display

2.4.1 Entering large Font Window

Click the patient information area in the patient section, and a menu appears. The first and the second items on the menu are: **Display the window in large font**, **Display all windows in large font**. The first menu command is to view one window in large font and the second one is to view all windows in large font. You can view a window or all current windows in large font mode by clicking on the menu commands (Figure 2-4).

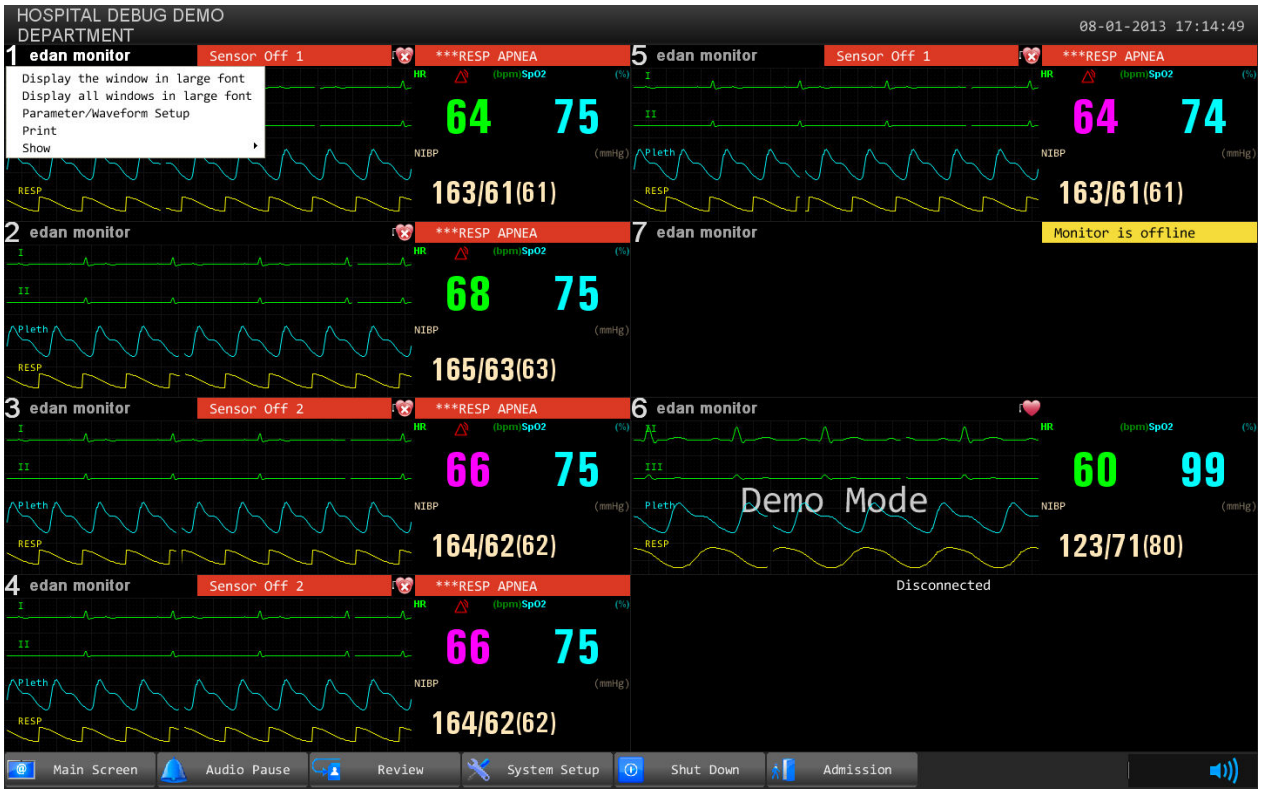


Figure 2-4 Large Font Menu

When you want to view one bed's parameters in large font, you can select the first command. After clicking on the menu, the parameters of the bed will be displayed in large font as shown in Figure 2-5.

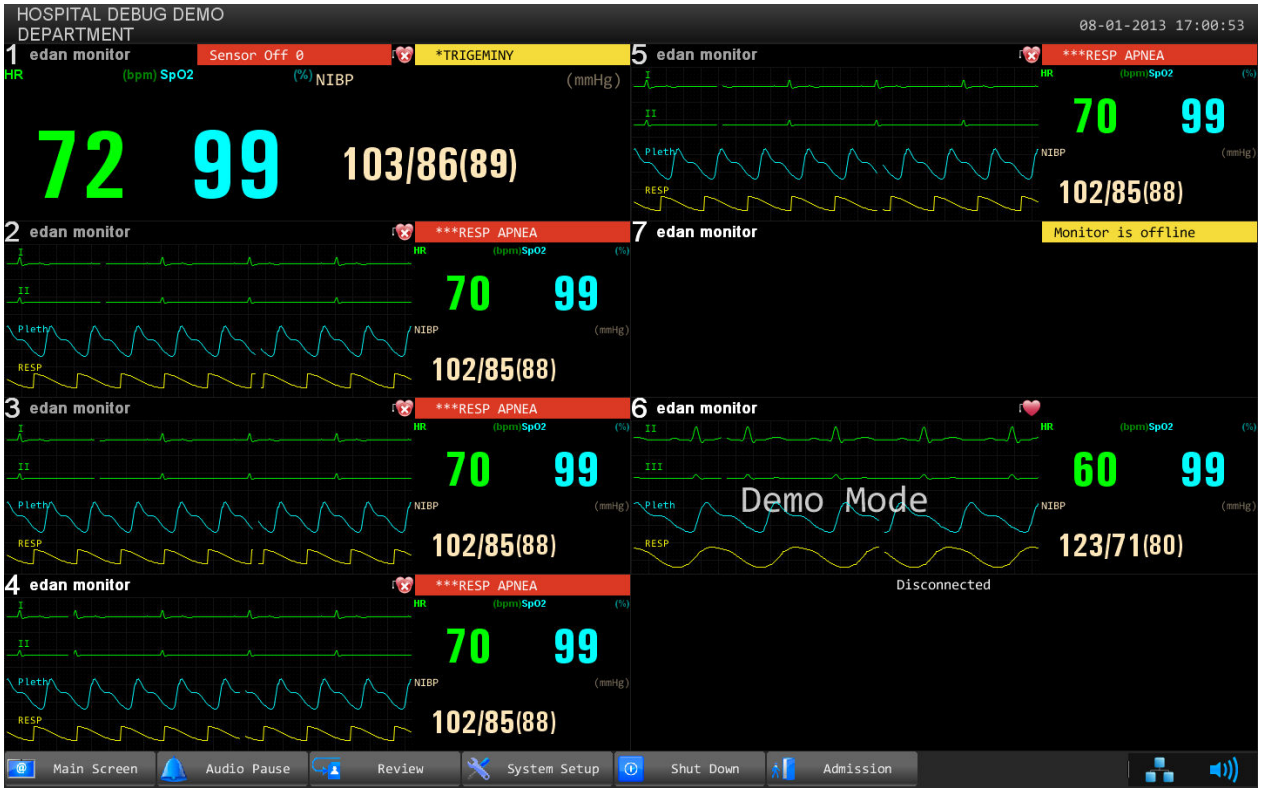


Figure 2-5 Viewing One Window in Large Font

When you want to view all parameters of current beds in large font, you can select the **Display all windows in large font** command. After selecting the command, the parameters of current beds will display in large font (Figure 2-6).

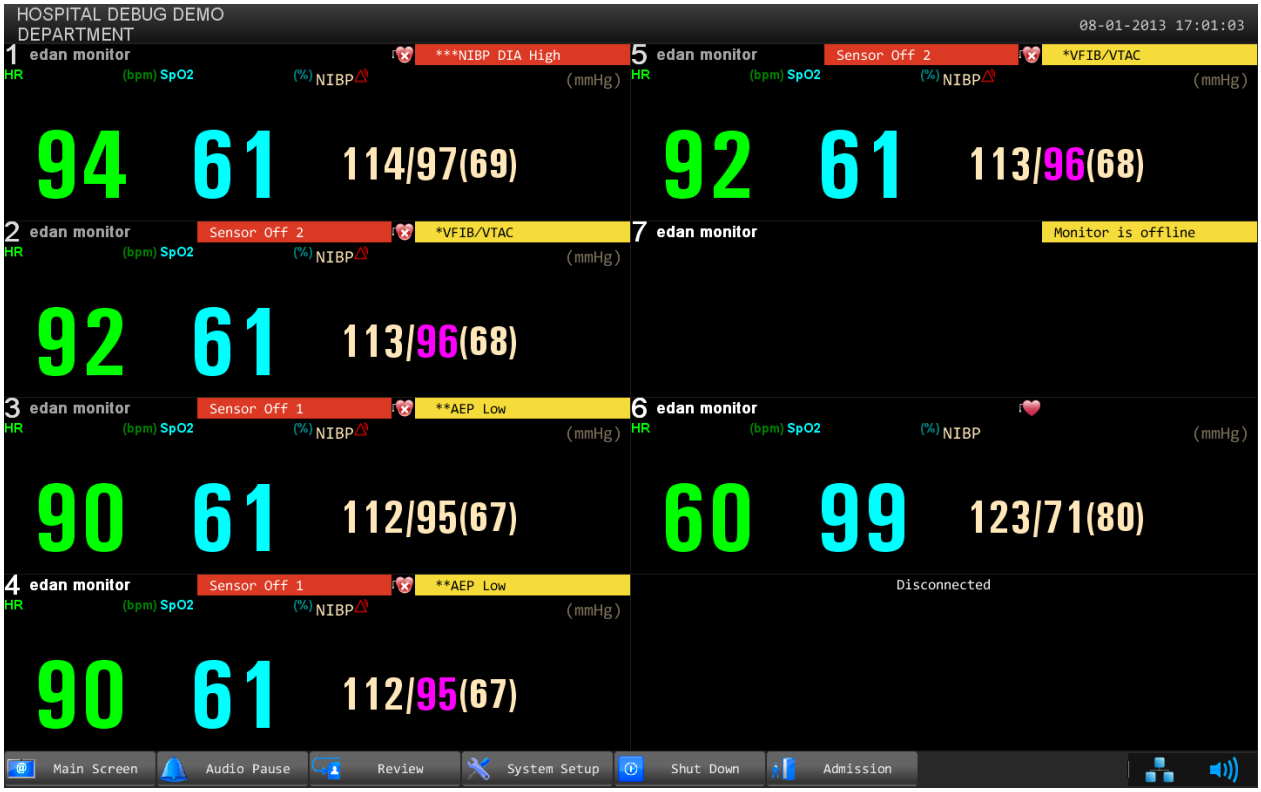


Figure 2-6 Viewing All Windows in Large Font

2.4.2 Closing Large Font Window

Click on the bed number on the main screen, and the large font menu pops up. The user can close the large font window by clicking on the first menu command. All current windows in large font can also be closed by clicking on the second menu command.

Chapter 3 Basic Operations

3.1 General

The basic function of the ENSEMBLE CMS is to realize the monitoring of multiple patients at the same time. Its basic monitoring information includes:

- Display one group of waveforms in the physiological information transmitted from up to 64 bedside monitors
- Display one group of parameters in the physiological information transmitted from up to 64 bedside monitors
- Display the latest alarm messages in the alarm information transmitted from up to 64 bedside monitors

The ENSEMBLE CMS realizes its basic monitoring functions by means of patient sections on the main screen.

3.2 Operating Method

3.2.1 Starting monitoring

NOTE:
Before starting the system, please verify that the watchdog has been installed. Otherwise, you may fail to access the system.

When all of its components are correctly connected, press the power button on the front panel of the device. The power indicator on the front panel lights up and the device performs hardware self-test. If the device works normally, the main screen appears. If the device detects abnormity during self-test, it beeps to show alarm and displays error information on the screen. In this case, you should record the error information, shut down the device and contact technical representative of MENNEN MEDICAL LTD.. After the system self-test is completed, you will access the ENSEMBLE CMS system interface and the system will also finish the environment self-test automatically. Meanwhile, the system will sound Do-Do-Do, a test sound. The user should set the volume system and confirm that the volume of the system can be heard clearly.

CAUTION

1 Ensure that the sound equipment is always in a state of activation.

2 The audio adapter and network adapter should be correctly installed, or you may not access the ENSEMBLE CMS.

NOTE:
Ensure that the ENSEMBLE CMS system can give the test sound after startup.

3.2.2 Shutting down the system

It is important to shut down the system properly. Follow this simple procedure to properly shut down your system. This prevents inadvertent errors from occurring during system shut down.

The ENSEMBLE CMS can work continuously for a long time. You do not need to shut it down in order to achieve a longer working life.

You should follow the procedure to shut down the ENSEMBLE CMS.

Method 1:

Select **Shut Down** on the main menu and enter the password. Confirm the password by clicking **OK**, and the ENSEMBLE CMS as well as the operating system will be shut down.

Method 2:

Select **System Setup** > **User Maintain,** and enter the password; select **Other Setup.**

- Select **Shut Down**: the ENSEMBLE CMS as well as the operating system will be shut down.
- Select **Return to Windows**: you will exit from ENSEMBLE CMS, but the operating system will not be shut down.

WARNING

1 Shut down the system by strictly observing the shutdown procedure to avoid serious result.

2 Although UPS is an optional configuration of this system, if you really force to turn off the UPS, it results in system failure and hence affects the operation of next time.

3 If power cut-off occurs, turn off the system before the UPS exhausts its electricity.

CAUTION

Hospitals without a stable power source should use a UPS to provide power to the ENSEMBLE CMS. The UPS must not be turned off. When there is a power failure, the system should be shut down by following the specified shutdown procedure before the UPS is exhausted. If the system has a sudden power failure, system failure may occur and consequently the system may work correctly next time or even have a serious result.

NOTE:
If you forget the password, please contact the technical representative of MENNEN MEDICAL LTD..

3.2.3 Patient Management

3.2.3.1 Admitting a Patient

Once ENSEMBLE CMS starts up and the bedside monitor is properly connected with

ENSEMBLE CMS, the system will prompt the user to admit patients by displaying the number of pending patients at the information area.

You can admit a patient by either of the methods below:

Method 1:

Click **Admission** on the main menu to display the pending patient list which contains the patients to be admitted. Select the patients you want to admit from the list. Click the **Admission** button at the bottom of the pending patient list to complete patient admission. The patients who have been chosen will be monitored by ENSEMBLE CMS.

Method 2:

Click anywhere in a disconnected patient section to display the menu on which you point to **Admission** and from the submenu select a bed No. of which the bedside monitor will be assigned to this patient section.

For the bedside monitor that has been offline due to network problems and is networked with ENSEMBLE CMS again, you need not admit the patient of this monitor. This monitor will be automatically online in the patient section to which it has been assigned.

WARNING

For bedside monitors that have been networked with ENSEMBLE CMS for the first time, you have to complete patient admission by using the methods mentioned above, which enables the monitors to be online and observed by ENSEMBLE CMS. Otherwise, the monitors will not be online on ENSEMBLE CMS, and the monitoring data will not be saved by ENSEMBLE CMS.

3.2.3.2 Changing Patient Information

You can change the patient information on ENSEMBLE CMS when you find the information incorrect. To modify the patient information, choose **Single Bed View** > **Patient Mgmt**, enter the correct information in the appropriate fields and click **Update Monitor** when you have finished modifying.

3.2.3.3 Switching Patient Section

- For a disconnected patient section (refer to Figure 2-2), click anywhere in it and choose a patient to be assigned to this section from the patient list.
- For a connected patient section, select **Show** from the list shown in Figure2-4, and choose another bedside monitor from the patient list; the chosen bedside monitor will be displayed in this patient section.

3.2.3.4 Discharging a Patient

- When the monitor is connected to ENSEMBLE CMS, you may choose **Single Bed View** > **Patient Mgmt** > **Discharge** to discharge a patient.
- When the monitor is disconnected with ENSEMBLE CMS, you may discharge a patient from the patient list. Refer to *5.1.1 Discharging a Patient* for more information.

3.2.3.5 Transfer a Patient

Select **Single Bed View** > **Patient Mgmt** >**Transfer** , and you will see a list of online patients. From this list, select a patient whose bed will be considered as the destination bed and click **OK**, and then the current patient will be transferred to the destination bed.

NOTE:

Transferring a patient to the destination bed will at the same time discharge the selected patient on the destination bed.

3.2.3.6 Monitoring Statistics

The monitoring statistics of the selected patients will be shown in the patient management window. The monitoring statistics covers the total monitoring time for waveforms and trends, the number of alarm events, the number of NIBP measuring, the number of C.O. measuring, the number of 12-lead analysis and the number of Quick TEMP measuring.

Click **Analysis**, the system will:

- Analyze the number of high and low limit alarms for each physiological parameter and analyze the percentage of the limit alarms of the parameter in all limit alarms.
- Analyze the number of arrhythmia events for each type of arrhythmia and analyze the percentage of a certain type of arrhythmia.
- Analyze the average value, maximum/minimum value, and measure time of the maximum/minimum value for the trend values.

3.2.4 Mouse operation

Usually, we use the following terms to describe mouse operation:

Left-key:

1. Click: move mouse to the target, then quickly press left-key once and release it.
2. Double-click: move mouse to the target, then quickly press left-key twice and release it.
3. Drag: move mouse to the target, press left-key and move to the destination and then release it.

Right-key:

1. Click: move mouse to the target, then quickly press right-key once and release it.
2. Double-click: move mouse to the target, then quickly press right-key twice and release it.

3.3 Patient Section

Patient section is used to display the real-time monitoring data transmitted from bedside monitors including one, two, three or four selected waveforms, a group of selected parameters and alarm of the bedside monitor, etc. Besides, in this area, you can also select the waveform and parameter group.

ENSEMBLE CMS can provide up to 64 patient sections with two displays. The user can select the number of patient sections to be displayed on the monitor.

The patient section can be divided into five areas including physiological waveform area, parameter value area, alarm information display area, patient information display area and status information area of bedside monitor. And the user can perform various functions through the patient section, including single bed view control.

- Waveform display area: display a group of waveforms. The waveform name is displayed on the upper left part of the waveform.
- Parameter display area: display the parameter information about the viewed bed. Due to the limited display space, you shall properly choose a group of parameters to better make use of the display area.
- Alarm information area: display the alarm information of the patient.
- Status information of bedside monitor.
- Patient information.

Due to the limited display space of the patient section, users can select a maximum of four waveforms and four parameters to be displayed. To set the displayed waveforms and parameters, you can select **Parameter/ Waveform Setup** from the list shown in Figure 2-4; also, you may select the tag **Parameter/ Waveform Setup** in the Single Bed window. Refer to *4.9 Setting Waveforms and Parameters* for more information.

For detail information, please refer to the chapter about viewing single bed.

NOTE:

1 Due to the delay of network transmission, the waveform viewed at the ENSEMBLE CMS has a delay of 5 seconds compared with the waveform generated at the corresponding bedside monitor.

2 Due to the operating system schedule, the waveform scan of the ENSEMBLE CMS might be suspended for about 20 milliseconds in very few occasions. After the suspension, waveform scan will go back to normal status. The quality of patient monitoring during the suspension will not be affected.

3.4 System Setup

The System Setup function is used to modify the display information at the patient section according to the real requirements. By using this function, you can observe the waveform, parameter, and the parameter list as your desire. There are **Common Setup**, **User Maintain**, and **Factory Maintain** to be set.

3.4.1 Common Setup

It is mainly used to make some conventional monitoring settings, such as parameter unit setup, color setup and layout setup.

3.4.1.1 Parameter Unit Setup

The user can change the unit of **IBP**, **NIBP**, **CO_2**, **(AG) CO_2**, **(AG) O_2**, **CO, TB** and **TEMP**. For example, to change the unit of IBP, please select **Main Screen** > **System Setup** > **Common**

Setup > **Param Unit Setup**, and select the desired unit among **mmHg** and **kpa** from the pull-down list at the right of IBP.

3.4.1.2 Color Setup

The user can change the display color of all parameters and the other information of the parameter is displayed as the same color. And the information includes waveform name, gain and filter, real-time value (upper limit and lower limit), review waveform and so on. To change the color of the parameter:

1. Please select **Main Screen** > **System Setup** > **Common Setup** > **Color Setup**, and click on the **Color Setup** button on the interface to enter the color setup.
2. And select the parameter from **Param Select** and select the desired color from the **Color Setup** on this interface.
3. After this, click on **OK** to exit the function.

3.4.1.3 Layout Setup

The user can set the bed numbers to be viewed on the screen through the button. To change the screens to be viewed, please select **Main Screen** > **System Setup** > **Common Setup > Layout Settings** and choose the desired bed number **4**, **6**, **8**, **10**, **12**, **14**, **16**, **32**, **64** from the drop-down list of display bed.

NOTE:
Two screens are needed if you want to simultaneously display the information of 64 bedside monitors.

3.4.1.4 Help

Help information is available on this interface.

3.4.2 User Maintain

To access the settings interface of user maintain, you have to input a user password. The default password is “abc”.

3.4.2.1 Monitor Batch Settings

You can configure the alarm limit, alarm switch and alarm level for a group of bedside monitors. You need to choose a patient type from **Adult**, **Pediat** or **Neonat** before you configure the alarm settings in **Templet of Alarm Limit Adjusting Range**. Choose the monitors needing to be configured in the right pane in which you may see a list of bedside monitors, and click **Config**. The configuration in the left templet pane will be applied to the chosen monitors.

Besides, from the right pane, you can choose a monitor whose alarm settings will serve as the source of batch settings for other monitors. Select one monitor in the right pane and click **Obtain Monitor Configuration** to obtain its parameter alarm settings. The obtained configuration will be displayed in the left templet pane. Choose the monitors needing to be configured in the right pane and click **Config** to complete batch settings.

NOTE:

1 The function of batch setting is not available for all monitors. If the monitor is labeled as **Not Supported** in the **Compatibility** column in the right pane, this function is not available for this monitor.

2 If the patient type set in **Templet of Alarm Limit Adjusting Range** is different from the one set on the bedside monitor to be configured, the system may fail to set the configuration for the monitor.

3 The prompt message **Success** only indicates success in setting the configuration for current activated parameters on the monitor.

3.4.2.2 Date/Time Setup

The user can set the correct date and time and their desired format. There are three kinds of date and time format: **yyyy-MM-dd**, **dd-MM-yyyy**, **MM-dd-yyyy**, two kinds of time format: **HH-mm-ss** (24 hours) and **hh-mm-ss tt** (12 hours), and three date separator: /, **-** and**.** To change the date and time setup, please select **Main Screen** > **System Setup** > **Common Setup** > **Date Time Setup,** and select the desired settings from the right menu**.** The time and date displayed on the main screen will also change after change the date and time setup and their format.

NOTE:
The user must restart the system to make the change effective.

3.4.2.3 Alarm Setup

Alarms, triggered by a physiological sign that appears abnormal or by technical problems of the monitor, are sent to the ENSEMBLE CMS by the monitors and then indicated to the users by the ENSEMBLE CMS. All alarms originally come from the monitors. The prompts coming from the ENSEMBLE CMS are displayed in the system prompt area on the upper screen. The user can enable/disable alarm mute function by selecting/ deselecting the **Alarm Mute** check box. When **Alarm Mute** is not selected, the alarm Mute is disabled. When **Alarm Mute** is selected, the alarm mute function is enabled. The icon is displayed at the top area of the screen. You can set the audio alarm mute duration to 1min, 2min or 3min from the drop-down list.

The user can set alarm sound intervals by selecting **Main Screen** > **System Setup** > **User Maintain** > **Alarm Setup,** and set the desired intervals from the drop-down list of **High Alarm Interval (s)**, **Med Alarm Interval (s)** and **Low Alarm Interval(s)**.

NOTE:
Once a new alarm occurs, the system will neglect the existing setting of alarm mute and generate a new alarm.

3.4.2.4 Changing Language

To change the display language, please select **Main Screen** > **System Setup** > **User Maintain,** and input the correct password. Select **Language Setup** and select the desired language from the drop-down list**.**

NOTE:
The user must restart the system to make the change effective.

3.4.2.5 HL7

Users can set the interval for HL7 data to be sent and set the format of HL7 packing data sent by ENSEMBLE CMS. The interval can be set to 1 to 120 minutes. HL7 data is sent in the format of HL7 Lower Level Protocol by default. If the item **XML** is selected, the data sent by ENSEMBLE CMS will be packed in the XML format.

NOTE:

HL7 data is sent via the port 9100 by default.

3.4.2.6 Database Backup

For detailed information about database backup, refer to *8.1 Database Backup*.

3.4.2.7 Other Setup

On this interface, you can:

- Set **Hospital Info.** and **Department**. The hospital information and department will be displayed at the top left corner on the main screen.
- Choose to display or conceal the grid in the View window by selecting or clearing the check box of **Display Grid on View**.
- Return to Windows.
- Switch off the system.

3.4.2.8 User Password Setting

To modify the password, enter the old password in the **Old Password** filed and a new one in the **New Password** field, after which you have to confirm the new password to complete the modification.

NOTE:

If you forget the password, please contact the technical representative of MENNEN MEDICAL LTD..

3.4.2.9 About

It offers information about the software compiled time and software version.

Chapter 4 Viewing Single Bed

The display setup function is used to modify the display information at the patient section according to the real requirements. By using this function, you can observe the waveform, parameter, and the parameter list as your desire. To change the display setup, click on any area of the patient section, the **Patient Mgmt**, **Single Bed View**, **Wave Review**, **Alarm Review**, **Trend Review**, **NIBP Review**, **Parameter/waveform Setup**, **Alarm/NIBP Setup**, **12-L Review, CO Measure Review, Review Quick Temp** and **Calculation** items are displayed.

4.1 Setting Patient Information

There are two ways to modify the patient information:

- Modify the patient information via the monitor. For more information, please refer to the monitor's operation manual.
- Modify patient information via the ENSEMBLE CMS.

In the patient management window, the user can modify the patient information, such as **Serial No.**, **Patient Name**, **Type**, **Gender**, **Bed No.**, **Date of Birth** and so on. After editing the information, click on the **Update Monitor** button to update the changes on the monitor. The patient information can be printed when the user click on **Print**.

NOTE:
If you have changed the patient type via the ENSEMBLE CMS, the patient type on the monitor will be changed accordingly.

4.2 Hiding/Showing Multi-lead Waveform

After clicking on any area on the patient section, the **Single Bed View** interface is displayed. The patient name, bed No., patient type and monitoring waveform are displayed on the single bed view. To view multi-lead waveforms interface, please click on **View Selection > Multi-lead** on the interface. To hide it, click on it again and the multi-lead waveforms disappear on the interface.

4.3 Real-time Printing

To print real-time data from ENSEMBLE CMS, click **Print** in the Single Bed window or select **Print** from the list shown in Figure 2-4. After you select **Print**, ENSEMBLE CMS starts to collect data for printing and the system will indicate **Collecting Data…** at the top of the main screen. After the system completes 11-second data collecting, a dialog box for printing setup will appear. The printout includes the 11-second waveform data starting from the time chosen as the beginning time for printing, data of all physiological parameters at the time you select **Print** and the latest NIBP measurements.

4.4 Short Trend Review

After entering the single bed view interface, click on **View Selection > Trend Screen** and the short trend will be displayed on the left of the interface. Click this area and a dialog box of short trend settings will pop up. You can set the display mode of the short trend with the optional items in **Param Select** and **Interval**. You may select the desired parameters needed to be displayed

from the drop-down list of **Param Select**. Also, you can set the interval of the short trend by choosing from **1h**, **2h**, **4h**, **8h** and **12h** in the drop-down list of **Interval**.

4.5 Freeze

In the **Single Bed View** window, you can freeze the waveform displayed in this window to analyze waveforms of interest by clicking **Freeze** and unfreeze the waveform by clicking **Unfreeze**.

The freeze time and a timeline will also be displayed in the window. You can use the arrow buttons ◀ and ▶ beside the timeline or drag the pointer on the freeze wave to review more details.

You can review a frozen waveform of 3-minute period in length.

4.6 OxyCRG

In the **Single Bed View** window, click **View Selection** > **OxyCRG**, and the OxyCRG window will be open. You can switch the display between respiratory rate and respiratory waveform by clicking **RR** and **RESP**. You can also set the interval of the OxyCRG to 1 minute, 2 minutes or 4 minutes.

4.7 Setting Wave Review

After click on **Wave Review** on this screen, the bed No., name, gender and type and wave settings are displayed. To change the displayed waveform, select **Select Wave** on the screen and a list of available waveforms will be shown. You can select a waveform by ticking its check box. By default, there are 4 waveforms displayed on this screen.

4.7.1 Setting Wave Speed

By clicking on the **Wave Speed** on this screen, you can set the width of waveforms displayed in the waveform area. Available options are **6.25mm/s**, **12.5mm/s**, **25mm/s** and **50mm/s**. Changing wave speed will affect the time length of the waveform area.

4.7.2 Refreshing Waveform

For the details about the refreshing waveform, please refer to the section about refreshing waveform.

4.7.3 Print

For the details about the printing waveform, please refer to the section about printing waveform.

4.8 Setting Alarm Review

For the details about the alarm review, please refer to *5.3 Alarm Review*.

4.9 Setting Trend Review

For the details about the trend review, please refer to *5.4 Trend Review*.

4.10 Setting NIBP Review

For the details about the NIBP review, please refer to *5.5 NIBP Review*.

4.11 Setting Waveforms and Parameters

The **Setup** function is used to modify the display information at the patient section according to the real requirements. By using this function, you can observe the waveform and the parameter as your desire.

4.11.1 Setting Waveforms to be Displayed

The screen can display 4 waveforms maximumly at a time. To change the waveforms displayed on the screen, please click on any area of the patient section to enter the setting screen of the single bed patient and select **Setup**. And tick the check box of the desired wave name and click on **Update Wave Setup** to confirm this operation.

4.11.2 Setting Parameters to be Displayed

The screen can display 4 parameters maximally at a time. To change the parameters displayed on the screen, please click on any area of the patient section to enter the setting screen of the single bed patient and select **Setup**.

- Adding a parameter to be displayed

  To add a new parameter to be displayed, select the desired parameter name in **Available Params** and click on **Add** to add it into **Current Params**, and then click on **Refresh ParamGroup** to update the parameters displayed on the patient section.

- Removing a parameter displayed

  To remove a parameter displayed, select the parameter in the **Current Params** box, and click on **Remove** and **Refresh ParamGroup.**

- Setting Parameter Order for Display

  To adjust the display position of the parameter, select the parameter name in the **Current Params** box, and click on **Move UP** or **Move Down**. To make the change valid, click on **Update ParamGroup.**

NOTE:

Due to the limited display space, the displayed waveforms and parameters of each patient section will decrease as the displayed patient sections increase. If you want more waveforms and parameters to be displayed on the screen, please modify the display layout by reducing the displayed patient sections.

4.12 Bilateral Control in Patient Section

4.12.1 Controlling NIBP Setup of Bedside Monitor

Click on **Alarm/NIBP Setup** on the single bed view screen to access the bi-control interface. Here you can modify the measurement mode and measurement interval of NIBP. The operation steps are shown as follows：

1. Click on the **NIBP Setup** button on the bilateral control interface;
2. Choose the desired measurement mode or measurement interval ;
3. Click on the **Update Monitor** button to validate changes.

4.12.2 Controlling Alarm Setup of Bedside Monitor

Click on **Alarm/NIBP Setup** on the single bed view screen to access the bi-control interface. Here you can modify the alarm settings including the alarm switch, alarm level and alarm limits. The operation steps are shown as follows：

1. Click on the **Alarm Setup** button on the bilateral control interface;
2. Choose the parameter of interest and change the corresponding alarm settings;
3. Click on the **Update Monitor** button to validate changes.

Chapter 5 Review

ENSEMBLE CMS is capable of searching and reviewing the history data of patients. It includes trend review, alarm review, wave review, NIBP review, 12-L Review, CO measure review, Quick Temp review and patient information review. By clicking on the **Review** button on the main interface, you can enter the review interface.

5.1 Patient List

Select **Online Database Source**, you can review the monitored patients' information, including online-patient review and history patient review. There are **Patient Review** and **History Patient Review** available. **Patient Review** shows the online patients. **History Patient Review** shows the history patients that have been discharged. The ENSEMBLE CMS is capable of query and review the data of the monitored patients.

Select **Offline Database Source**, you can review the backup patient list. Refer to *8.2 Reviewing Backup Database* for more information.

You can select a patient from the list and click the **Patient Mgmt** tab to review detailed information of this patient. Also, you can double click the patient name in the list to open the patient management window.

5.1.1 Discharging a Patient

Discharging a patient is to terminate monitoring a patient and admit a new patient. There are two ways to discharge a patient:

Click on **Review** > **Patient List** to access the review interface for all patients. Select a patient needed to be discharged from the patient list below and click on the **Discharge** button on the interface. A dialog box will consequently pop up and ask for your confirmation. Click on **Yes**, the patient is discharged; click on **No**, the patient will remain.

If a patient is discharged from the **Patient Review** list, partial information of his or hers can still be reviewed in the **History Patient Review** list. If a patient is deleted from the **History Patient Review** list, all information of this patient will be completely deleted from the system.

CAUTION

If you delete a patient from the **History Patient Review** list, his or her data will be completely removed from the system.

5.1.2 Querying a Patient

To querying a patient's information, input one item of the patient's information, such as serial No., patient name and doctor, and click on **Query**. If the patient information is saved, the corresponding information is displayed on the screen.

5.2 Wave Review

The ENSEMBLE CMS can review the change process of the physiological waveform of one patient in the latest 72 hours. And the system can provide 72-hour waveform review.

To use 72-hour waveform review, please click on **Main Screen** > **Review** > **Wave Review.** On this screen, you can:

- Review normal waveforms or compressed waveforms
- Set wave speed
- Select wave
- Refresh waveform
- Print

5.2.1 Reviewing Normal Waveforms

Normal waveform review is available to all parameter waveforms. In the normal waveform review window, the waveform is displayed with the same altitude and speed of the real-time waveform.

You can select **Show parameters**/**Hide parameters**. If you select **Show parameters**, the related parameter value will also be displayed accompanying the waveform you choose.

In this window, waveforms can also be presented by automatically sliding forward.

5.2.2 Reviewing Compressed Waveforms

Compressed waveform review is only available to ECG waveforms. In the compressed waveform review window, the altitude of the ECG waveform will be compressed so that you can review the waveform containing longer time of data.

5.2.3 Setting Wave Speed

By clicking on the **Wave Speed** button, you can set the width of waveforms displayed in the waveform area. Available options are **6.25 mm/s**, **12.5 mm/s**, **25 mm/s** and **50 mm/s**. Changing wave speed will affect the time length of the waveform area.

5.2.4 Refreshing Waveform

Waveform will not update automatically. Therefore, if you want to view up-to-date waveform, you have to refresh them manually. Clicking on the **Refresh** button will refresh the waveform.

5.2.5 Selecting Waveform

Click on the **Select Wave** button, and a list of available waveforms will be shown. By default, all waveforms are selected. You can deselect a waveform by ticking its check box.

NOTE:

The 72-hour full disclosure waveform storage will occupy a lot of hard disc. Therefore, the user shall be cautious to add additional waveform to the selecting waveform setup.

5.2.6 Print

To print the waveform displayed on the current screen, please select **Print** on the screen to print it by the laser printer.

5.3 Alarm Review

Alarm table and waveform may be generated when the ENSEMBLE CMS makes secondary notification for the alarm happening at the bedside monitor. Alarm review helps the clinician observe the details of the monitoring information. Alarm information can be stored by the user and thus become important alarm event. An alarm strip in the alarm review is a 16-second waveform.

5.3.1 Locking and Unlocking Alarm Information

When the user thinks that an alarm is very important, he/she can save it by locking the alarm information with a symbol √ on the alarm review interface. The symbol √ will appear to its right on this interface when the alarm is locked. The locked alarm cannot be deleted automatically. You can click on the symbol √ to unlock the locked alarm, the symbol √ will disappear.

5.3.2 Printing Alarm Information

If the user wants to print alarm table, he/ she can click on **Print** on the interface to print it by a laser printer.

NOTE:

1 The important alarm events can be deleted but not automatically .The non-important alarm events can be automatically replaced by new alarm events when they have accumulated to a certain amount.

2 The alarm stripe displays the physiological waveform at 25mm/s when an alarm takes place.

5.3.3 Sequencing the Alarm List

You can sequence all alarms ascendingly or descendingly by clicking on the heading of any column:

- **Alarm Time**: Clicking on it will sequence all alarms ascendingly or descendingly by time.
- **Alarm Information**: Clicking on it will sequence all alarms ascendingly or descendingly by parameter.
- **Alarm Level**: Clicking on it will sequence all alarms ascendingly or descendingly by level.

At the same time, one of the following symbols will appear to the right of the heading:

- The symbol ▲ indicates ascending sequence, and
- The symbol ▼ indicates descending sequence.

5.3.4 Annotating Alarm

You can add notes to illuminate an alarm. To annotate an alarm, select a certain alarm stripe and you will see the title **Alarm Note** on the bottom of the alarm review interface. Move the cursor 1cm left to the title **Alarm Note** and a pop-up input box in which you can input detailed information for the alarm will appear. After you complete your notes, move the cursor out of the area of the input box, and ENSEMBLE CMS will automatically save the input information.

NOTE:

Input characters are limited to 256.

5.3.5 Filtering Alarm Events

You can filter alarm events by selecting or clearing the check boxes before the items in the **Alarm Level** list and in the **Param Select** list. The **Alarm Review** window will only display the alarm events whose alarm level /levels has/have be selected and the alarm events of selected parameters.

5.4 Trend Review

Clicking on the **Trend Review** button will enter the trend review button, through which you can store and review up to 240 hours of trend data. Change of trends can be observed through the graphic and tabular.

On this interface, you can:

- set the resolution
- view parameters selectively
- refresh the data
- print

5.4.1 Setting Resolution

You can select a time period as the resolution for viewing the graph and table as required. Options are **1s**, **5s**, **1m**, **5m**, **15m**, **30m**, **60m**, **Display Time Points for NIBP Measurements** and **Display Time Points for Quick TEMP Measurements**. To change the resolution, select **Resolution Setting** on the interface and select the desired option from the list.

5.4.2 Viewing Parameters selectively

In the parameter list **Param Select**, you can select modules or parameters by ticking their check boxes as required. Only the selected parameters are displayed in the graph or table.

When a parameter module is selected or unselected, all of its parameters will be selected or unselected accordingly.

5.4.3 Refreshing Data

Trend data will not update automatically. Therefore, if you want to view up-to-date trend data, you have to refresh them manually. Click on the **Refresh** button to refresh the data to up-to date. After refreshing them, the select status and order of parameters remain unchanged.

5.4.4 Printing Trend Review

Clicking on **Trend Review** > **Print** > **Print Trend Table**/ **Print Trend Graph**, you can print the trend table or the trend graph. By default, the system will print the latest data.

5.4.5 Selecting Trend Table, Trend Graph

To review the trend table only, the user can select View Selection on the interface and then select the Trend Table option from the drop-down list. To review the trend graph, the user can select View Selection on the interface and then select the Trend Graph option from the drop-down list. To review the trend table and trend graph, the user can select View Selection on the interface and then select the Trend Table, Trend Graph option from the drop-down list.

5.5 NIBP Review

Results of four latest NIBP measurements are displayed in the NIBP area in the **Single Bed View** window.

To review earlier NIBP measurement results, click the **NIBP Review** button and enter the NIBP review interface, through which you can view up to 720 groups of NIBP measurements of a patient.

The NIBP review window displays **Serial No.**, **Measure Time**, **SYS**, **DIA**, **MAP** and **PR** for each measurement. Additionally, in this window you can:

- Click **Show parameters**, and the measurement values of all physiological parameters at the measure time specified in the selected item will be shown in the lower portion of the window. If you click **Hide parameters**, these measurements values will not be displayed.
- Refresh
- Print out the current page
- Print out all pages

5.6 12-Lead Review

Select **12-L Review** and you can review up to 720 groups of 12-lead analysis results of the current patient in this window.

In the **12-L Review** window, the following data is available: HR, PR Interval, QRS Duration, QT/QTC Interval, P/QRS/T, RV5/SV1, the value of RV5+SV1 and Diagnosis Result.

Select a diagnosis result from the list and select **Waveform** on the toolbar, the related 12-lead ECG waveform will be shown.

You can print the diagnosis result list and waveform.

5.7 C.O. Measure Review

Select **CO Measure Review** and you can review up to 720 groups of C.O. measurement of the current patient in this window.

In the **CO Measure Review** window, measure results are arranged chronologically on the left. Select a measure result and the measure value as well as the curve will be displayed on the right. A maximum of six groups of measure results can be displayed simultaneously.

At the lower part of the window, the average values of C.O and CI of the selected measure results are displayed.

You can print the selected measure results.

5.8 Quick Temp Review

Select **Quick TEMP Review** and you can review up to 720 groups of Quick TEMP measurement in this window. The Quick TEMP measure result and measure time are available. You can also print the Quick TEMP measurement list.

Chapter 6 Alarm Management

6.1 General

Alarms, triggered by a physiological sign that appears abnormal or by technical problems of the monitor, are sent to the ENSEMBLE CMS by the monitors and then indicated to the users by the ENSEMBLE CMS. All alarms originally come from the monitors. The prompts coming from the ENSEMBLE CMS are displayed in the system prompt area on the upper screen.

6.1.1 Physiological Information Alarm

It includes parameter alarm and arrhythmia alarm.

Physiological information alarm arouses the doctors' attention by means of visual and audible methods specified in harmonized international standard. Visual method is realized basically by the way of lightening or flicking of the color light. Audible method is realized by the sound for different levels.

Physiological alarms are implemented by alarm limits, which define a range in which a certain physiological parameter is considered to be in the normal status. When a parameter value is beyond the range, the system will consider it to be in an abnormal status and consequently give an alarm.

6.1.2 Technical Alarm

Technical alarms refer to the technical alarms of bedside monitor. Technical alarms of bedside monitor refer to alarms other than physiological alarms, including hardware failure, communication error, lead off, etc. For these technical alarms, the system presents four different types of audible and visual prompts.

When a group of technical alarms (for example, transducer falls off) produced by multi-parameter monitors, a piece of alarm prompt information in scrolling mode will appear on the main screen of ENSEMBLE CMS. In addition, the ENSEMBLE CMS will sound low- level alarm and the corresponding bedside monitor status indicator will also show low-level signal color.

NOTE:
The alarm signal will be delayed for no more than 5 seconds.

6.2 Alarm Level

Alarm level reflects the severity of an alarm. The ENSEMBLE CMS has three levels of alarm:

- High level alarm
- Medium level alarm
- Low level alarm

The ENSEMBLE CMS indicates different levels of alarm by varying the color of the alarm area in the patient section.

6.3 Alarm Mute

Alarm mute means that when an alarm occurs, the system will not give an alarm sound but only maintain a visual prompt.

6.4 Alarm Voice Pause

Alarm Voice Pause means that during a period of time, when an alarm occurs, the system will not give alarm announcement.

The duration of alarm voice pause can be set to 1 minute, 2 minutes and 3 minutes. And the duration setting is introduced in *3.4.2.2 Alarm Setup*.

When the duration of alarm pause has lasted for the preset-time, the system will stop the status of alarm pause and resume normal alarm automatically.

NOTE:

1 Once a new alarm occurs, the system will neglect the existing settings of Alarm Mute or Alarm Voice Pause and generate a new alarm.

2 The alarm mute and alarm pause function is only valid for ENSEMBLE CMS itself. ENSEMBLE CMS cannot silence or pause the bedside monitor's audible alarm.

6.5 Alarm Prompt/Response

Alarm information can be prompted by means of visual and audible methods. Because the alarm information is very important and timely response to the alarm information is highly required, the ENSEMBLE CMS provides the following methods to indicate to the user the occurrence of the alarm.

- Background refreshing

  When a physiological alarm occurs, the system will warn the user by refreshing the background of the corresponding patient section of the bedside monitor into different colors.

- Background color of the alarm area in the patient section

  The red color indicates the occurring of high level alarm.

  The yellow color indicates the occurring of medium or low level alarm.

- Alarm sound

  If the mute setup is ineffective, the system will warn the user about the alarm with the alarm sound.

  The alarm sound can be:

  High level alarm: sound "DO-DO-DO DO-DO DO-DO-DO DO-DO";

  Medium level alarm: sound "DO-DO-DO";

  Low level alarm: sound "DO- ".

6.6 Alarms for Networking Status

When the monitor is online or offline, the system will indicate it with a low level alarm sound.

If the monitor is offline without being discharged, the system will indicate it with a low level alarm sound at an interval of 1 minute.

Chapter 7 Printing

7.1 Printing Report with a Printer

ENSEMBLE CMS can output the reports by equipped with a laser printer. HP LaserJet Series printers are recommended. The laser printer working with the ENSEMBLE CMS is independent of the mainframe. The printer has its independent power supply. It is connected to the mainframe via a USB interface or a network (wired or wireless).

The laser printer generates the following types of printing:

- Waveform review printing
- Alarm wave printing
- Alarm table printing
- Trend graph printing
- Trend table printing
- NIBP review printing
- Printing for drug calculation, hemodynamic calculation, oxygenation calculation, renal function calculation and ventilation calculation
- Patient information printing
- 12-lead analysis result printing
- C.O. review printing
- Quick TEMP review printing

NOTE:
ENSEMBLE CMS only supports printing on A4 paper.

7.2 Preview/Settings

7.2.1 Preview

Before the reports are printed, you can preview them on the screen. You will access the preview interface after you select the function of printing. If a report consists of more than one page, you may select a certain page to preview by turning to the page you want. Besides, you can adjust the zoom setting by choosing a certain option from the drop-down list of the **SIZE.** Below is the preview interface of the wave review:

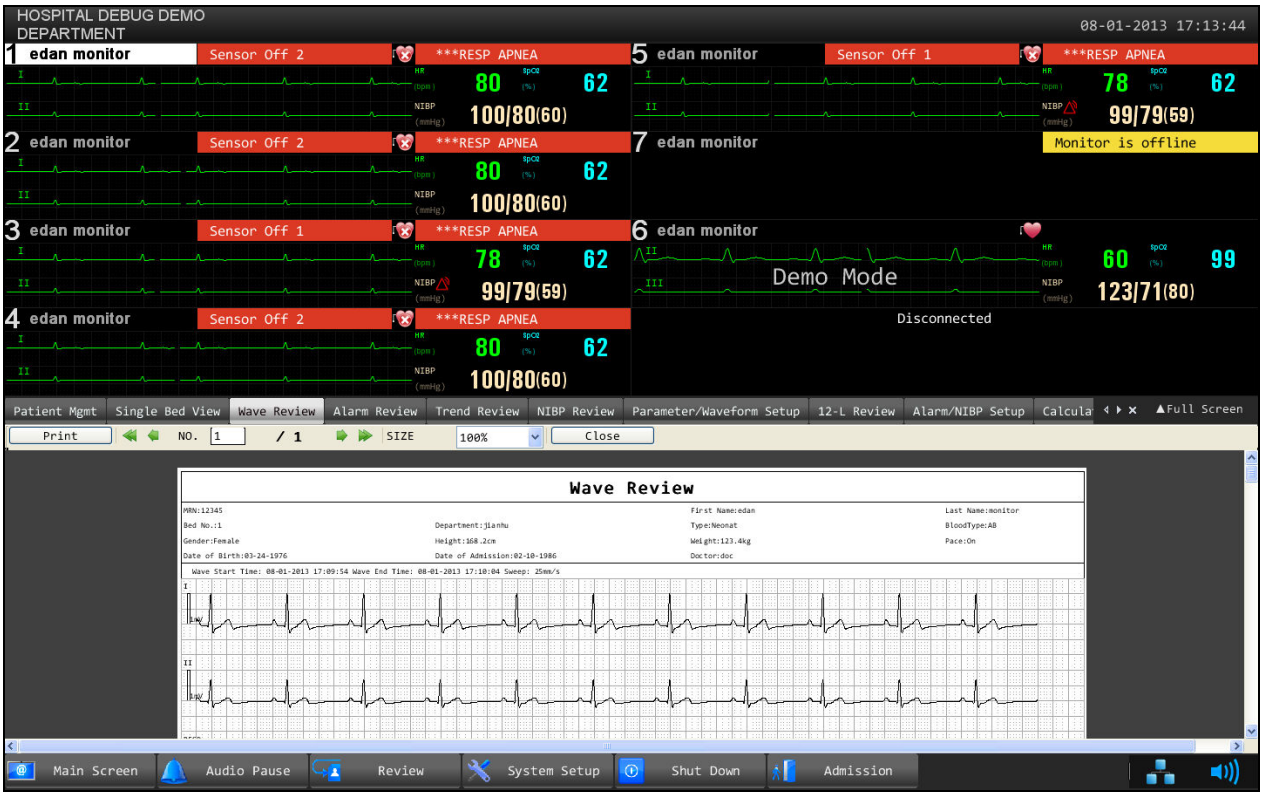


Figure 7-1 Preview

7.2.2 Settings

Click on **Print** on the preview interface and a dialog box will pop up as follows:

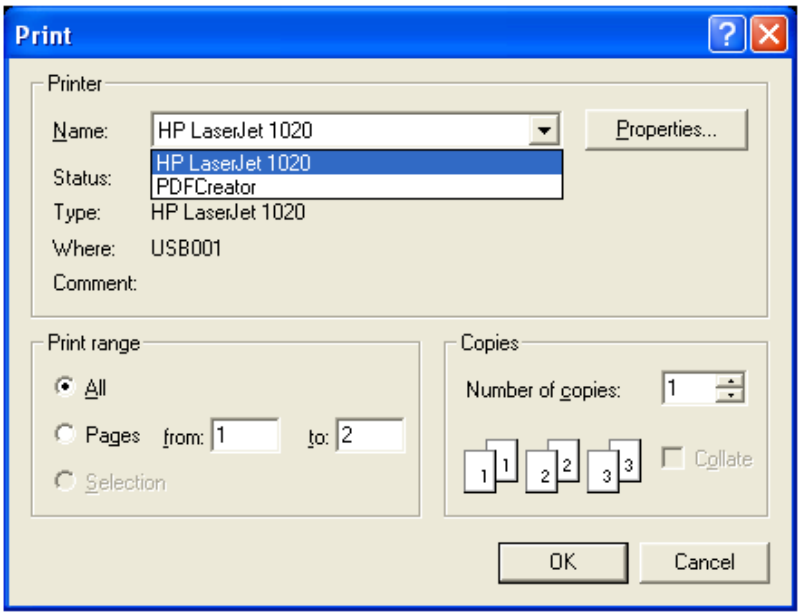


Figure 7-2 Settings

Select the printer, the print range and the number of copies in demand and then click on **OK** to confirm it.

7.3 Exporting the PDF File

ENSEMBLE CMS can export the PDF file by installing a PDF printer software. The software PDFCreator is recommended. You can obtain the installation version of PDFCreator in the ENSEMBLE CMS installation disk. Also, you may download it from the website http://www.pdfforge.org/pdfcreator.

To export the PDF file, please choose a PDF printer (for instance, PDFCreator) from the drop-down list when you select the printers (Figure 7-3), and then confirm it by clicking on **OK**.

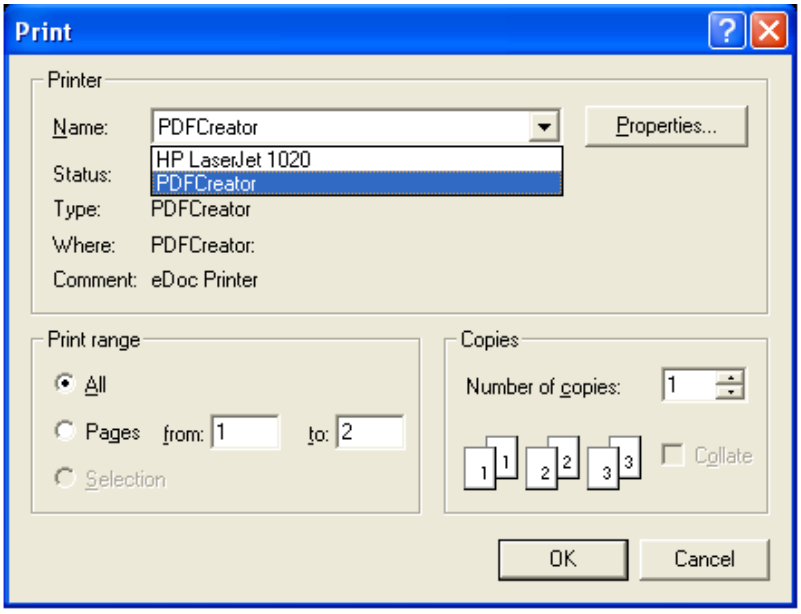


Figure 7-3 Select a PDF Printer

Chapter 8 Database Management

ENSEMBLE CMS provides database backup and review, which allows you to conveniently manage and maintain data.

8.1 Database Backup

To backup database, please select **Main Screen** > **System Setup** > **User Maintain,** and input the correct password. Select **Database Maintain** and click on the button **Browse** to choose a directory for backup file storage. Then click on **Backup Database** to start database backup.

NOTE:

1 During database backup, ENSEMBLE CMS automatically stops its patient monitoring.

2 ENSEMBLE CMS will restart automatically after it completes database backup.

3 If the check box indicating "**Empty local database after backup is completed"** is ticked, ENSEMBLE CMS will empty the local database after database backup is completed.

8.2 Reviewing Backup Database

ENSEMBLE CMS allows you to review the backup data at any time.

To review backup data, select **Review** > **Patient List**, and select the directory for storing backup file from the drop-down list of **Offline Database Source**. For more information about review, refer to *Chapter 5 Review*.

NOTE:

1 It takes about 3 to 10 seconds for ENSEMBLE CMS to load the backup data.

2 During reviewing backup data, discharging or deleting patients is unavailable.

Chapter 9 Calculation and Titration Table

9.1 General

ENSEMBLE CMS provides functions including drug calculation and titration table, hemodynamic calculation, oxygenation calculation, renal function calculation and ventilation calculation; the calculation results can be printed out. Click on **Calculation** in the status of single bed view to access the drug calculation screen.

ENSEMBLE CMS is able to save a maximum of 100 groups of results for every type of calculation. In the calculation window, you can use the **Save** button to save the calculation results and use **Calculation Result List** to review each calculation result.

9.2 Drug Calculation

From the **Drug** drop-down list, you can select one to calculate its amount, liquid volume, concentration, etc.

- Drug A
- Drug B
- Drug C
- Drug D
- Drug E
- AMINOPHYLLINE
- DOBUTAMINE
- DOPAMINE
- EPINEPHRINE
- HEPARIN
- ISUPREL
- LIDOCAINE
- NIPRIDE
- NITROGLYCERIN
- PITOCIN

NOTE:
Drug A, Drug B, Drug C, Drug D and Drug E are user-defined drugs.

The calculation procedure is listed below:

1. Confirm whether the patient type is correct and the weight is entered.
2. Select a drug to be calculated from the drug list.
3. Input correct parameter values under the direction of a doctor.
4. Select **Basic, Dose Type** and **Step** for titration table.
5. Click on the **Calc** button, the calculation result will be displayed in the drug parameter area and titration table.

WARNING

1 Be sure to input correct parameter values. The user must verify the correctness of the calculations displayed on the screen before using them.
2 The calculations in the titration table are subject to the drug calculations, therefore, the correctness of the drug calculations must be ensured. Besides, the basic, step and dose type should be ensured correct.
3 We assume no responsibility for the results arising from incorrect inputs and operations.

9.2.1 Drug Calculation Formula

Formulas for drug calculation are:

Concentration = amount / volume

Flow rate = dose / concentration

Total dose = dose × duration

Total volume = flow rate × duration

WARNING

Prior to performing drug calculation, you must confirm that the above formulas are what you need. Our company will not be liable for any consequence resulted from using inappropriate formulas.

Relationship between calculation units:

1 g = 1000 mg

1 mg = 1000 mcg

1 K unit = 1000 units

1 M unit = 1000 K units

WARNING

You must enter correct drug unit. Our company will not be liable for any consequence resulted from incorrect input.

9.2.2 Calculation of Titration Table

Calculation of titration table is included on the screen of drug calculation. The titration table is located at the lower part of the drug calculation screen. The method for calculation of titration table is:

1. The core method for the calculation of titration table is: concentration = dose / flow rate. The calculating method of titration table is to keep the fixed concentration, change the dose to calculate the flow rate or change the flow rate to calculate the dose. Concentration here is obtained from drug calculation.
2. The titration table can be displayed by way of dose and rate. You can enter the rate step from 1-10. There are four options available for dose unit: mg/hour, mg/min, mg/Kg/hour and mg/Kg/min, among which mg will vary with the unit changes in drug calculation.
3. The calculating result of titration table is displayed in the list. You can click on the scroll bar to browse more calculating results.

WARNING

The calculating result of titration table depends on the calculating result of drug. First of all, the calculating result of drug should be accurate. And then, the calculating result of titration is concerned with the input titration control parameters and the calculating formula. Therefore, you must ensure the correctness of all these mentioned operations. Our company will not be liable for any consequence resulted from improper operations.

9.3 Hemodynamic Calculation

9.3.1 Input Parameters

Abbreviation	English Full Name/Description
PAWP	Pulmonary artery wedge pressure
CVP	Central venous pressure
HR	Heart rate
AP MAP	Mean Artery Pressure
LV_D	Left Ventricular Diameter
PA MAP	Pulmonary artery mean pressure
HT	Height
WT	Weight

9.3.2 Output Parameters

Abbreviation	English Full Name/Description
BSA	Body surface area
SV	Stroke volume
SVI	Stroke volume index
SVR	Systemic vascular resistance

SVRI	Systemic vascular resistance index
PVR	Pulmonary vascular resistance
PVRI	Pulmonary vascular resistance index
LCW	Left cardiac work
LCWI	Left cardiac work index
RCW	Right cardiac work
RCWI	Right cardiac work index
LVSW	Left ventricular stroke work
LVSWI	Left ventricular stroke work index
RVSW	Right ventricular stroke work
RVSWI	Right ventricular stroke work index
EF	Ejection fraction

9.4 Renal Function Calculation

9.4.1 Input Parameters

Abbreviation	English Full Name/Description
HT	Height
WT	Weight
URK	Urine pstassium
Posm	Plasm osmolality
SCr	Serum creatinine
URNa	Urinary sodium
Uosm	Urine osmolality
UCr	Urine creatinine
UUN	Urine urea nitrogen
Urine	Urine
SerNa	Serun sodium
BUN	Blood urea nitrogen

9.4.2 Output Parameters

Abbreviation	English Full Name/Description
URNaEx	Urine sodium excretion
CNa	Clearance of sodim

FENa	Fractional excretion of sodium
CH2O	Free water clearance
URKEx	Urine potassium excretion
CCr	Creatinine clearance rate
FEUr	Fractional Excretion of Urea
Na/K	Sodium potassium ratio
CUUN	Urine urea nitrogen clearance rate
Cosm	Osmolar clearance
U/P osm	Urine to plasma osmolality ratio
BUN/SCr	Blood urea nitrogen creatinine ratio
U/SCr	Urine-serum creatinine ratio

9.5 Oxygenation Calculation

9.5.1 Input Parameters

Abbreviation	English Full Name/Description
HT	Height
WT	Weight
C.O.	Cardiac output
FiO2	Percentage fraction of inspired oxygen
PaO2	Partial pressure of oxygen in the arteries
PaCO2	Partial pressure of carbon dioxide in the arteries
SaO2	Arterial oxygen saturation
PvO2	Partial pressure of oxygen in venous blood
SvO2	Venous oxygen saturation
Hb	Hemoglobin
CaO2	Arterial oxygen content
CvO2	Venous oxygen content
VO2	Oxygen consumption
RQ	Respiratory quotient
ATMP	Atmospheric pressure

9.5.2 Output Parameters

Abbreviation	English Full Name/Description
BSA	Body surface area
VO2	Calc Calculated oxygen consumption
C(a-v)O2	Arterial venous oxygen content difference
O2ER	Oxygen extraction ratio
DO2	Oxygen transport
PAO2	Partial pressure of oxygen in the alveoli
AaDO2	Alveolar-arterial oxygen difference
CcO2	Capillary oxygen content
Qs/Qt	Venous admixture
C.O. calc	Calculated cardiac output
Pa/FiO2	PaO2/FiO2
AaDO2/PaO2	AaDO2/PaO2
Pa/AO2	PaO2/PAO2
DO2I	Oxygen Delivery Index
VO2I	Oxygen Consumption Index
CaO2 calc	Calculated Arterial oxygen content
CvO2 calc	Calculated Venous oxygen content

9.6 Ventilation Calculation

9.6.1 Input Parameters

Abbreviation	English Full Name/Description
FiO2	Percentage fraction of inspired oxygen
RR	Respiration rate
PeCO2	Partial pressure of mixed expiratory CO2
PaCO2	Partial pressure of carbon dioxide in the arteries
PaO2	Partial pressure of oxygen in the arteries
VT	Tidal volume
RQ	Respiratory quotient
ATMP	Atmospheric pressure
PIP	Peak Inspiratory Pressure
PEEP	Positive End-Expiratory Pressure

9.6.2 Output Parameters

Abbreviation	English Full Name/Description
Cdyn	Compliance dynamic
PAO2	Partial pressure of oxygen in the alveoli
AaDO2	Alveolar-arterial oxygen difference
Pa/FiO2	PaO2/FiO2
AaDO2/PaO2	AaDO2/PaO2
Pa/AO2	PaO2/PAO2
MV	Minute volume
VD	Volume of physiological dead space
VD/VT	Physiological dead space in percent of tidal volume
VA	Alveolar volume

Chapter 10 CMS-WEB Observer

10.1 General

The CMS-WEB Observer system is a medical information device applied in clinical monitoring field. It realizes remote monitoring by reviewing real-time and history data from central monitoring system through web page. A CMS-WEB network system is constructed by connecting multiple monitors and ENSEMBLE CMS central monitoring systems. Being the center of the monitoring network, the system realizes remote monitoring by collecting, processing, and analyzing the physiological information from the central monitoring systems. Medical staff can obtain patient information by visiting the server of ENSEMBLE CMS via the browser.

The CMS-WEB Observer displays patients' physiological information collected by the ENSEMBLE CMS central monitoring system. The system displays information of up to 32 bedside monitors from the ENSEMBLE CMS.

NOTE:

The CMS-WEB Observer is only available via the hospital local area network.

10.2 Typical Screens of the CMS-WEB

The CMS-WEB shares similar screen features with the ENSEMBLE CMS. The main screen of the CMS-WEB has three areas. At the top of the screen is the area displaying the system prompt information. The middle part is the main monitoring area. The bottom part is the system menu area. Figure 10-1 shows the main screen of the CMS-WEB.

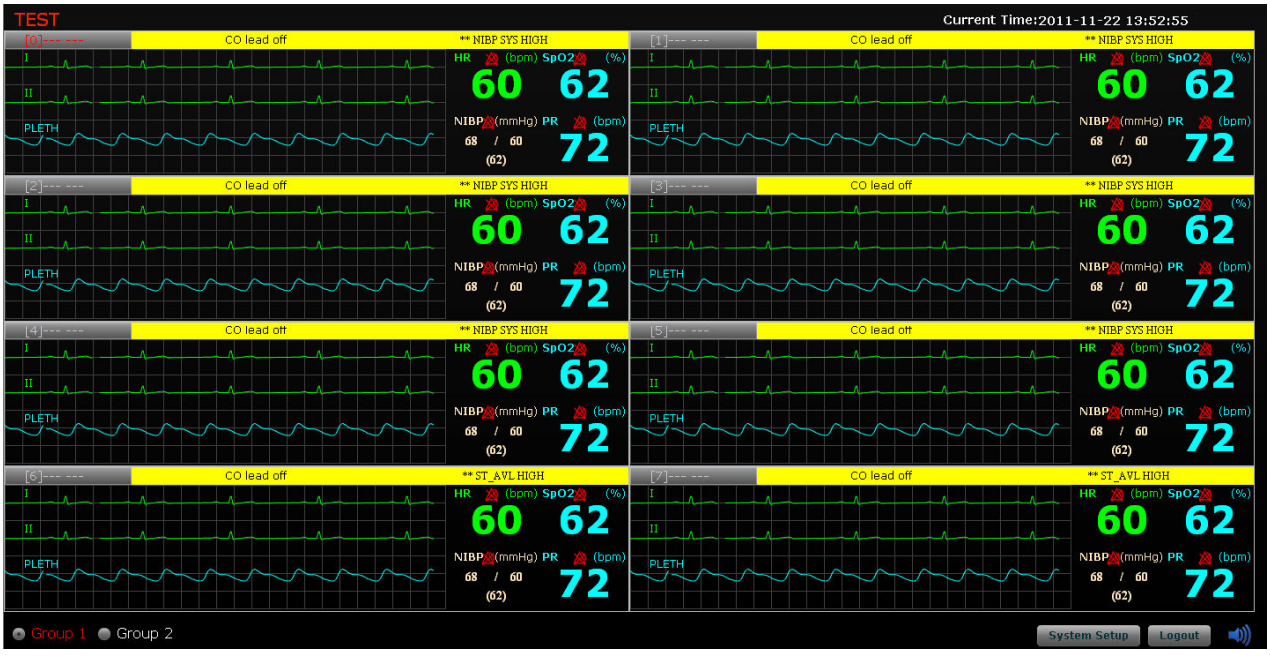


Figure 10-1 Main Screen of CMS-WEB

Structure of the main screen:

1. Information area

Displaying the hospital name and current system time.

2. Main monitoring screen

Indicating the current status of each bedside monitor:

- The onscreen bedside monitors are networked.
- The red color in the alarm area of the patient section indicates the bedside monitor has high priority alarm.
- The yellow color in the alarm area of the patient section indicates the bedside monitor has a medium or low priority alarm.

When four or less four bedside monitors are networked, the layout of patient sections will be of single row as Figure 10-2 shows:

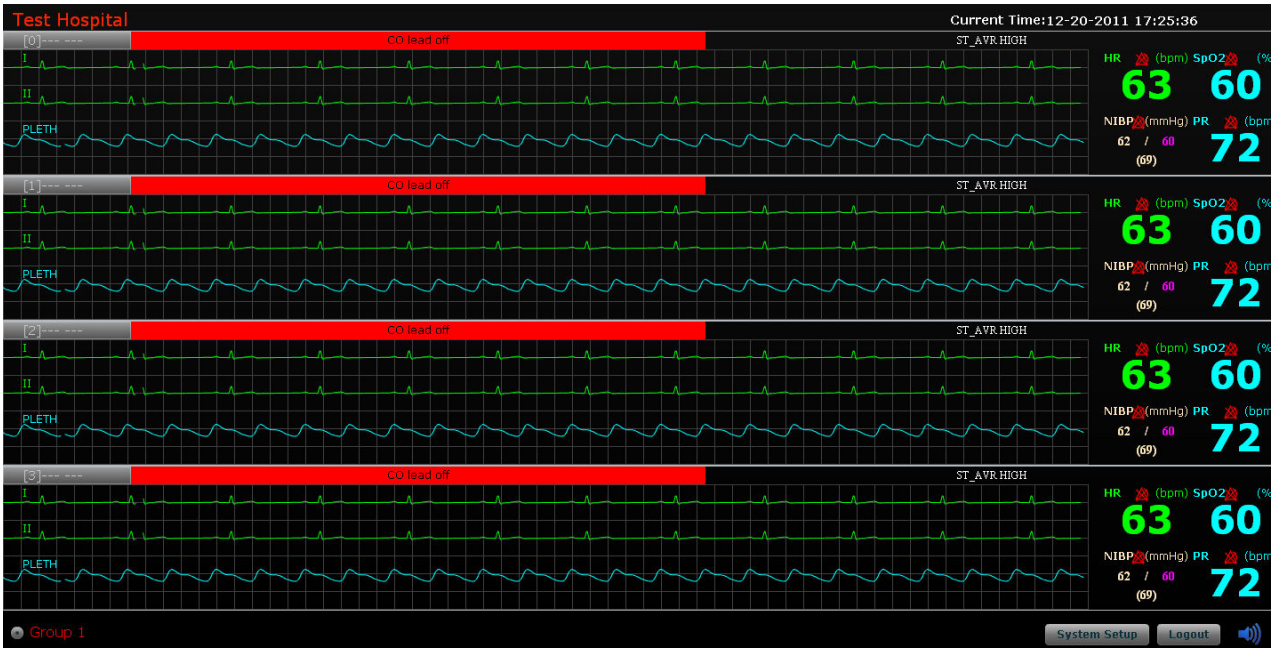


Figure 10-2

When over four bedside monitors are networked, the screen displays patient sections as shown in Figure 10-1 with a maximum of eight bedside monitors.

NOTE:

The number of displayed waveforms on each patient section will vary with the resolution of your computer monitor. The maximum number of waveforms displayed on each patient section is four. It is recommended to use computer monitors with the resolution of 1028×1024 or 1440×900.

3. Main menu

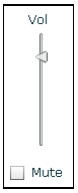
The main menu (Figure 10-3) is at the bottom of the screen. Click on it to access corresponding windows or perform corresponding functions.

Figure 10-3

If one patient section is selected for single bed reviewing, the button **Return Main Screen** will appear at the bottom left corner, selecting which can return to the main screen.

3. Control icons

Control icon area includes the following icons:

Icons	Operating method
	Click on it to return to the main screen.
	Click on it to enter the system setup menu.
	Click on it to log out of the system.
	Click on it, the volume adjustor icon  appears. Tick the **Mute** check box, the entire system become mute until a new alarm occurs. To deselect the silence function, tick the **Mute** check box again. Additionally, the user can drag the volume adjustor to your desired volume.

10.3 Starting/ Shutting Down the System

NOTE:

Before starting the system, make sure the ENSEMBLE CMS has been installed in the computer. Otherwise, you cannot use the CMS-WEB.

10.3.1 Starting the System

Before starting the system, make sure the computer in which the CMS-WEB Observer server is installed has been installed with the IIS (Internet Information System) groupware as well. Assume that the IP address of the server is 192.168.11.138; to start the CMS-WEB, you should enter http://192.168.11.138/ENSEMBLE CMS/ into the address bar of the browser and input user name as well as password in the login window to access the system.

NOTE:

1 The default user name for administrator is “admin”; default password is “test”. You can change the user name and password after accessing the system.

2 The administrator is able to create other administrators and users. The default password for creating new users is “123456”.

10.3.2 Shutting Down the System

You can shut down the system via either of the following two methods:

Method 1: Click on the **Logout** button at the bottom right corner onscreen.

Method 2: Click on the button at the top right corner onscreen.

10.4 System Setup

You can access the system setup menu by clicking on **System Setup** and configure the following items: **Common Setup** and **Administrators Setup**.

NOTE:
The available setup items may vary with different users due to different users' access authority. Both **Common Setup** and **Administrators Setup** are available for the administrator while only **Common Setup** is available for general users.

10.4.1 Common Setup

10.4.1.1 Setting User Information

Select **System Setup** > **Common Setup** > **Personal Infor.**, and you can change the user name, name, gender, department, and so on.

10.4.1.2 Setting Password

Select **System Setup** > **Common Setup** > **Password Change**; you can change the login password.

10.4.1.3 Setting Parameter Unit

Select **System Setup** > **Common Setup** > **Unit Setup**; you can change the units of IBP, NIBP, CO_2, AG CO_2, AG O_2, C.O.TB and TEMP.

10.4.1.4 Setting Multi-Bed Waveform

Select **System Setup** > **Common Setup** > **Wave In Multi-bed**; you can set the physiological waveforms displayed on the patient sections. In this window, the left column displays the waveform names from which you can choose; the right column displays the waveform names which have been selected.

- Adding a waveform to be displayed:

To add a displayed waveform, choose one from the left column and click on **Add** so that it can be added to the right column.

- Deleting a displayed waveform

To delete a displayed waveform, choose one from the right column and click on **Remove** so that it can be deleted from the waveform display area.

NOTE:

1 You can only select a maximum of four waveforms to be displayed on each patient section. Also, the number of displayed waveforms is subject to the computer resolution.

2 You can only add or delete one waveform one time.

10.4.1.5 Setting Multi-Bed Parameter

Select **System Setup** > **Common Setup** > **Para In Multi-bed**; you can set the physiological parameters displayed onscreen. In this window, the left column displays the parameter names from which you can choose; the right column displays the parameter names which have been selected.

- Adding a parameter to be displayed

To add a displayed parameter, choose one from the left column and click on **Add** so that it can be added to the right column.

- Deleting a displayed parameter

To delete a displayed parameter, choose one from the right column and click on **Remove** so that it can be deleted from the screen.

NOTE:

1 You can only select a maximum of four parameters to be displayed on each patient section.

2 You can only add or delete one parameter one time.

10.4.1.6 Setting Wave Speed

Select **System Setup** > **Common Setup** > **WaveSpeed**; you can set the speed for a selected waveform. Choose one waveform from the **Wave Name** list and the chosen one will be highlighted as shown in Figure 10-4; then select a speed from the drop-down list of **New Speed**.

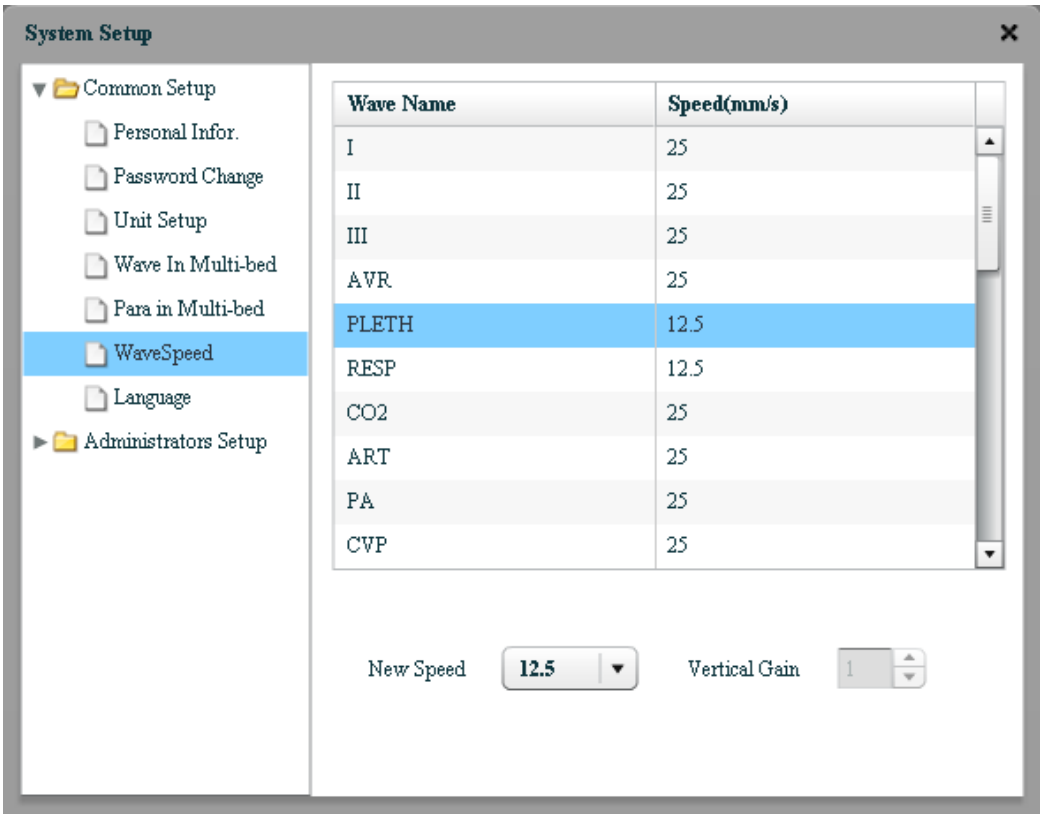


Figure 10-4 Wave Speed Setup

10.4.1.7 Setting Language

Select **System Setup** > **Common Setup** > **Language**, click on and select a language from the drop-down list.

NOTE:

To ensure the normal display of CMS-WEB, restart the system after you finish the language configuration.

10.4.2 Administrator Setup

10.4.2.1 User Management

Select **System Setup** > **Administrators Setup** > **User Manage**; the administrator can set the user access authority.

- Creating a user

In the **User Manage** window, input the **User Name**, **Name**, **User Type**, **Gender**, **Department** and so on, click on **Insert** and a new user will be created. The default password for creating users is 123456.

- Deleting a user

Select a user to be deleted from the user list, click on **Delete** and the user will be removed.

- Modifying user information

Select a user whose information is to be modified and enter new information for the user; then click on **Modify** to complete the modification.

NOTE:
The administrator cannot modify his/her information here. Refer to the section 10.4.1.1 for details.

- Resetting user password

Select a user whose password is to be reset and click on **Reset password**; confirm it by clicking on **Confirm** on the pop-up dialog box. The password will be reset to the default password.

10.4.2.2 Setting Date/Time Format

Select **System Setup** > **Administrators Setup** > **TimeFormat**, click on the button beside **Date Format** or **Time Format** and select a format from the drop-down lists.

10.4.2.3 Setting Waveform Refresh Type

Select **System Setup** > **Administrators Setup** > **Refresh Type**; you can set the refresh type of the real-time waveforms. Two options are available: **Pen Mode** and **Move Mode**. Click on the button and select one mode from the drop-down list.

10.5 Viewing Single Bed

Via the function of viewing single bed, you can check information of a patient. Click on any area of the patient section and you will access the single bed window. Available items including **Patient Infor**, **Single Bed View**, **Wave Review**, **Alarm Review**, **Trend Review** and **NIBP Review** will be displayed onscreen.

10.5.1 Patient Information

You may check patient information via **Patient Infor** window. CMS-WEB Observer displays the patient information collected by the ENSEMBLE CMS. You can only view the patient information via CMS-WEB but not modify them. The readings of **Height** and **Weight** will vary with the unit selection. Click on **Print** if you need to output the patient information.

10.5.2 Single Bed View

- Multi-waveform display

Click on **Multi-lead** in the window so that you can view multiple channels of waveforms displayed onscreen. Click on it again to switch to single waveform display mode.

- Freezing waveform

Click on **Freeze** in the window so that you can freeze the waveform displayed onscreen, which may help you analyze the waveform of interest. Click on **Freeze** again to unfreeze the waveform.

10.5.3 Waveform Review

In the **Wave Review** window, you can:

- Select waveforms;
- Set wave speed;
- Refresh waveforms;
- Set the starting time for printing;
- Print waveforms.

The system allows you to print the waveform with a maximum time of two minutes. If you have not set the starting time, the system will output the latest data by default. If you have set the starting time, the system will start to output data at the point of the set time.

NOTE:

The set starting time for printing will be invalid after the data is output.

For more details about waveform review, refer to relevant content for ENSEMBLE CMS in the section *5.2 Wave Review*.

10.5.4 Alarm Review

In the **Alarm Review** window, you can:

- Refresh alarm information;
- Print alarm list;
- Print alarm strip.

For more details about alarm review, refer to relevant content for ENSEMBLE CMS in the section *5.3 Alarm Review*.

10.5.5 Trend Review

In the **Trend Review** window, you can:

- Review trend data;
- Set resolution;
- Select parameters to be reviewed;
- Refresh data;
- Print trend graph and trend list;
- Set the display mode of the trend review window;
- Set the starting time for printing.

Printing trend graph: If you have not set the starting time, the system will output the latest data by default. If you have set the starting time, the system will start to output data at the point of the set time. The system allows you to output a maximum of 600 pieces of data.

Printing trend list: If you have not set the starting time, the system will output the latest data by default. If you have set the starting time, the system will start to output data at the point of the set time. The system allows you to output a maximum of 720 pieces of data.

NOTE:

The set starting time for printing will be invalid after the data is output.

For more details about trend review, refer to relevant content for ENSEMBLE CMS in the section *5.4 Trend Review*.

10.5.6 NIBP Review

In the **NIBP Review** window, you can view up to 720 groups of NIBP measurements of an online patient.

The NIBP review window displays **Serial No.**, **Measure Time**, **SYS**, **DIA**, **MAP** and **PR** for each measurement. Additionally, you can:

- Refresh;
- Print.

NOTE:

1 Make sure a PDF reader has been installed in your computer, which enables you to preview and open the printing document.

2 **CMS-WEB only supports printing on A4 paper.** Make sure you have set the paper size to A4 in the printing setup.

3 If the main menu is not displayed onscreen after clicking on the print button and return to the CMS-WEB screen, check your browser setup. For Firefox browser, select **Tools > Options > Tabs**, and tick the check box of **Always show the tab bar**.

Chapter 11 Safety

11.1 Control and Safety Index

Windows XP/ Windows 7 workstation, printer, UPS (optional), Keyboard, display and mouse should accord with the corresponding safety requirements. They are not suitable for installed in the patients' environment.

11.2 Characteristics

The standard ENSEMBLE CMS includes the following characteristics:

- Up to 240 hours of trend data storage and review
- Storage of patients' history data
- 72-hour full disclosure physiological waveforms
- 12-lead ECG display
- 12-hour short trend data
- Printing report
- Monitoring 64 patients simultaneously
- Connect patient monitor: M3, M3A, M50, M80, iM50, iM80, iM8, iM8A, iM8B, elite V8.
- Transfer waveforms, parameters, alarms, etc.

Chapter 12 Service

If you have any question about maintenance, technical specifications or malfunctions of devices, contact your local distributor.

Alternatively, you can send an email to MENNEN MEDICAL LTD. service department at: support@Mennen Medical Ltd..com.cn.

Appendix I Specifications

A1.1 Recommended Hardware Configuration

The minimum requirements of hardware configuration for the ENSEMBLE CMS are shown as below.

<table>
<tr><td>Components</td><td>Requirements</td></tr>
<tr><td>System</td><td>Meet the IEC/EN control requirements for ITE device</td></tr>
<tr><td>PC workstation</td><td>CPU: Intel Core 2 Duo 2.0GHz or above
Memory: 2G or above
Hard disk: 320GB or above
Display interface: 2
LAN port: 1 or above
USB port: more than one
OS: Windows XP (32 bit), Windows 7</td></tr>
<tr><td>Keyboard</td><td>PS/2 or USB keyboard</td></tr>
<tr><td>Mouse</td><td>PS/2 or USB mouse</td></tr>
<tr><td rowspan="2">Display</td><td>Specifications:
<table><tr><td>Dimensions (inch)</td><td>Resolution (pixel)</td></tr><tr><td>19(widescreen)</td><td>1440X900</td></tr><tr><td>*19 (regular-screen)</td><td>1280X1024</td></tr><tr><td>17 (widescreen)</td><td>1280X1024</td></tr><tr><td colspan="2">*Recommended</td></tr></table></td></tr>
<tr><td>Quantity:
For 1 to32 bedside monitors: one display
For 33 to 64 bedside monitors: two displays</td></tr>
<tr><td>Printer</td><td>LaserJet</td></tr>
<tr><td>UPS</td><td>1000 W</td></tr>
</table>

Network device specifications	Structure	Ethernet 802.3
	Device	Network switch
	Transmission rate	10M, 100M
	Transmitted information	Waveforms, parameters and alarms of all networked bedside monitors
	Compatible monitors	Patient monitors complying with MENNEN MEDICAL LTD. network protocol
	Maximum number of networked monitors	64
Speaker	Built-in speaker is recommended.	

CAUTION

Ensure that the computer hardware can meet the requirements of the software installation and running. Also, the video adapter, the audio adapter, the network adapter and their respective drivers should been installed well in the computer; otherwise, the software may not run normally.

NOTE:

1 The hardware specifications require the use of PC that complies with IEC/EN requirements for ITE equipment.

2 The configuration mentioned above is for reference and not permanent. MENNEN MEDICAL LTD. preserves the right to change and upgrade system settings.

A1.2 Software Performance

Trend	240-hour trend review for each bedside monitor 12-hour short trend dynamic display for each bedside monitor
Alarm waveform	720 pieces of parameter alarm waveforms for each bedside monitor
Alarm type	Physiological Alarm Technical Alarm
Alarm mode	3 levels of audible and visual alarms
Waveform storage and review	72-hour waveform for each bedside monitor

NIBP measurement storage and review	720 pieces of NIBP measurement for each bedside monitor
12-lead analysis results	720 pieces of 12-lead analysis results for each bedside monitor
C.O. measurements	720 pieces of C.O. measurement for each bedside monitor
Quick TEMP measurements	720 pieces of Quick TEMP measurement for each bedside monitor